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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 10/091,172 03/04/2002 ENDOV-55674 Juan I. Perez 9937 7590 **EXAMINER** 24201 12/10/2004 FULWIDER PATTON LEE & UTECHT, LLP BARRETT, THOMAS C HOWARD HUGHES CENTER **ART UNIT** PAPER NUMBER 6060 CENTER DRIVE TENTH FLOOR 3738

DATE MAILED: 12/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

					101
		Application	ı No.	Applicant(s)	
		10/091,172	<b>?</b>	PEREZ ET AL.	
Office Action Summary		Examiner		Art Unit	
		Thomas C.		3738	
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).					
Status					
1) Responsive to comm	nunication(s) filed on <u>26</u>	November 20	<u>04</u> .		
2a) This action is FINAL	☐ This action is FINAL. 2b)☐ This action is non-final.				
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims					
4) ⊠ Claim(s) <u>1-23</u> is/are 4a) Of the above clai 5) ⊠ Claim(s) <u>22 and 23</u> is 6) ⊠ Claim(s) <u>1-21</u> is/are 7) □ Claim(s) is/are 8) □ Claim(s) are s	m(s) is/are withdows/are allowed. rejected. e objected to.	rawn from con		·	·
Application Papers			·		
9) The specification is objected to by the Examiner.					
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.					
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).					
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.					
The dath of declaration is objected to by the Examiner. Note the distance ember tensor of terms is real.					
Priority under 35 U.S.C. § 11					
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>					
Attachment(s)					
1) Notice of References Cited (PT			4) Interview Summary Paper No(s)/Mail Da		
Notice of Draftsperson's Patent     Information Disclosure Stateme     Paper No(s)/Mail Date		00,	5) Notice of Informal F 6) Other:		O-152)

### **DETAILED ACTION**

### REQUEST FOR CONTINUED EXAMINATION

The request filed on November 26, 2004 for a Request for Continued

Examination (RCE) under 37 CFR 1.114 based on parent Application No. 10/091,172 is

acceptable and a RCE has been established. An action on the RCE follows.

### Response to Arguments

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "claim 1 requires *employing* the recited first sheath to have a first treatment component as well as to receive a subsequent treatment component") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Claims 1 and 18 are directed to a system for treating vasculature, not to a method. It does not matter *how* the system is *employed* as long as the prior art meets the **structure** of the claimed invention.

However, claims 22-23 are directed towards a method and are allowable over the prior art of record.

# Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7-9, 12, 15 and 16-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Martin (5,575,817). Regarding claims 1, 8 and 15, Martin discloses a system for treating vasculature at a repair site comprising a first treatment component (Figure 1, Reference Number 1), a first sheath or retractable membrane (Column 2, Lines 5-6) with a length sufficient to extend to a repair site and before being retracted, a first treatment component (Figure 1, Reference Number 7) and a loading capsule comprising the restraining sheath of the second section and a pusher assembly or catheter (column 2, Lines 18-22) with an inner tube (Figure 3). Martin further discloses that the first sheath and the restraining sheath of the loading capsule are configured to mate (Column 2, Lines 22-30) and therefore have approximately equal outer profiles. Regarding claims 2-4, Martin discloses that there is a plurality of subsequent treatment components (Figure 1, Reference Numbers 9 and 1) and that the first sheath is retracted to deploy the treatment components (Column 2, Line 15) after restraining the component in a compressed configuration (Column 4, Lines 8-10). Regarding claim 5, Martin discloses that the treatment component is self-expanding (Column 2, Lines 38-40).

Regarding claim 7, Martin discloses the use of a guide wire (Figure 3, Reference Number 19).

Regarding claim 9, Martin discloses that the pusher assembly or catheter is capable of simultaneously engaging a plurality of treatment components (Column 2,

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Art Unit: 3738

Lines 4-6), where the first section comprises the upper limb, first lower limb and a portion of the second lower limb (Column 1, Lines 46-49).

Regarding claims 12 and 16, Martin discloses that the pusher assembly, used to advance treatment components includes an inner tube.

Regarding claim 17, "wherein the first sheath remains within the vasculature..." is a limitation directed to an intended use, which does not result in a structural difference not met by Martin.

### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Martin (US 5,575,817). Regarding claim 10, Martin discloses a treatment system that includes a pusher assembly, or catheter, that has a tapered tip. Martin lacks the teaching of the tapered tip being flexible, however it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Martin to have a flexible pusher assembly tip to make navigation within the body lumen easier.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Martin (US 5,575,817) in view of Drasler et al. (US 6,451,051).

Regarding claim 11, Martin discloses a system for treating vasculature including restraining the first treatment component in a non-expanded form, however he lacks the teaching of cloverfolding the component. Drasler et al. teach of a foldable tubular endoprosthesis that can be cloverfolded (Figures 2C and 2D) so that it can be easily inserted into the vasculature in a compressed state. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Martin to have the treatment component cloverfolded so that it can be entered into the vasculature in a compressed state.

Claims 6, 18 and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin (USPN 5, 575, 817) in view of Leonhardt et al. (USPN 5,713,917).

Regarding claims 6 and 18 Martin discloses a system for treating vasculature including a pusher assembly, a loading capsule that is capable of mating with an introducer sheath (Column 2, Lines 22-30), however he lacks the teaching of an introducer sheath and having the first treatment component inserted through the loading capsule. Leonhardt et al. teach of a method for engrafting a vessel that includes a sheath introducer, through which all components are introduced into the lumen, so that only one sheath is necessary during the deployment procedure. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Martin to have the loading capsule mate with a single introducer sheath for the deployment of a plurality of graft components.

Regarding claim 20, Martin discloses the use of a guide wire (Figure 3,

Reference Number 19).

Regarding claim 21, Martin discloses that the treatment component is selfexpanding (Column 2, Lines 38-0).

### Allowable Subject Matter

Claims 22-23 are allowed over the prior art of record.

#### Conclusion

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE**FINAL even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas C. Barrett whose telephone number is (571) 272-4746. The examiner can normally be reached Tuesday-Friday between 9:00 A.M. and 6:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**Thomas Barrett**